

ClaimsWhat is claimed is:

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- 023
- 1004537-00000
- 1 1. A method of calcifying a section of soft tissue, dermis, pericardium, fascia, woven soft
2 tissue (as from skeletal muscle), urinary bladder membrane (UBM), or SIS implant
3 material, comprising contacting a section of said implant material with a calcium
4 solution, and thereafter contacting said section with a phosphate solution.
- 1 2. The method of claim 1, wherein said calcium solution is a saturated calcium
2 hydroxide, and said phosphate solution is phosphate buffer adjusted to approximately pH
3 7.0.
- 1 3. A method of calcifying implant material comprising the steps of:
2 a) contacting said implant material with a viral inactivating agent;
3 b) contacting said implant material with a decellularizing agent;
4 c) contacting said implant material with a saturated calcium hydroxide
5 solution; and
6 d) contacting said implant material treated by step c with a phosphate solution.
- 1 4. The method of claim 3 wherein said viral inactivating agent comprises , benzalkonium
2 chloride; said decellularizing agent comprises a solution comprising, by weight, about 1
3 percent tween 20 and about 0.5 percent hydrogen peroxide; and wherein said method
4 further optionally comprises sonicating said implant material during step b.
- 1 5. A calcified section of implant material made according to the method of claim 4.
- 1 623 6. An implant useful in orthopedic surgery comprising at least one block and at least one
2 section of flexible material attached to said at least one block.

1 7. The implant of claim 6, wherein said at least one block comprises an assembled
2 implant comprising at least two substantially planar segments, wherein at least one of
3 said at least two substantially planar segments comprises at least one slot defined thereon,
4 and wherein said at least two substantially planar segments are fastened together by
5 sliding said at least one slot of at least one planar segment over another substantially
6 planar segment.

1 8. The implant of claim 7, wherein said at least one block comprises a first substantially
2 planar segment and a second substantially planar segment, wherein said first and second
3 substantially planar segments comprise a slot longitudinally defined thereon such that
4 said first and second substantially planar segments comprise a slotted section and a body
5 section, and wherein said first and second substantially planar segments are fastened
6 together by sliding the slotted section of each over the body portion of the other.

1 9. The implant of claim 6, said implant comprising at least one assembled block, wherein
2 said assembled block is comprised of two or more segments made of mineralized bone,
3 demineralized bone or a synthetic material, or a combination thereof; and at least one
4 flexible band attached to said at least one assembled block, wherein said band is
5 comprised of a natural material or of a synthetic material.

1 10. The implant of claim 6, wherein said at least one section of flexible material is
2 comprised of dermis.

1 11. A bone-ended graft useful in orthopedic surgery comprising at least one bone block
2 and at least one section of flexible tissue attached to said at least one bone block.

1 12. The bone-ended graft of claim 11, wherein said flexible tissue comprises soft tissue,
2 dermis, pericardium, fascia, woven soft tissue, urinary bladder membrane, dura mater,
3 demineralized bone, or skeletal muscle.

1 13. The bone-ended graft of claim 11, wherein said flexible tissue is dermis.

1 14. The implant of claim 11, wherein said at least one block comprises a first
2 substantially planar segment and a second substantially planar segment, wherein said first
3 and second substantially planar segments are made of bone and comprise a slot
4 longitudinally defined thereon such that said first and second substantially planar
5 segments comprise a slotted section and a body section, and wherein said first and second
6 substantially planar segments are fastened together by sliding the slotted section of each
7 over the body portion of the other.

1 15. The bone-ended graft of claim 14, wherein said at least one bone block comprises
2 two or more longitudinal fins, and wherein said flexible tissue is attached to said at least
3 one bone block by contact with at least one of said two or fins.

1 16. The bone-ended graft of claim 11, wherein said at least one bone block is cut to
2 provide a groove sufficient to accommodate a fixation screw.

1 17. The bone-ended graft of claim 11, wherein said at least one bone block is shaped into
2 a dowel.

1 18. The bone-ended graft of claim 11, wherein said at least one bone block is 9mm,
2 10mm, 11mm, or 12 mm in diameter.

1 19. The bone-ended graft of claim 16, wherein said groove is a radius cut extending the
2 length of the bone block.

1 20. The bone-ended graft of claim 11, wherein said bone block has a thread profile
2 positioned on its surface in the groove.

1 21. The bone-ended graft of claim 11 wherein said tendon has a first end and a second
2 end, and wherein said one or more bone blocks comprises a first bone block attached to
3 said first end and a second bone block attached to said second end.

1 22. The bone-ended graft of claim 11 wherein said implant material is attached to said at
2 least one bone block by chemical annealing, chemical adhesive, suturing (optionally
3 through drilled holes in the bone), pinning to, or wrapping and tying the implant material
4 around the bone ends (and optionally applying a suitable adhesive).

1 23. The bone-ended graft of claim 11 wherein at least one of said at least one bone block
2 comprises two or more longitudinal fins extending from at least one end of said at least
3 one bone block.

1 24. The bone-ended graft of claim 23 wherein said at least one section of flexible tissue
2 passes along a first channel between adjacent fins, loops around a far end of the bone-
3 ended graft, and passes back along a second channel between adjacent fins, and attaches
4 to a section of itself to form a loop encircling the bone-ended graft.

1 25. The bone-ended graft of claim 23 wherein the processed implant material passes
2 through at least one hole in at least one fin of the bone-ended graft, and attaches to a
3 section of itself to form a loop encircling the bone-ended graft.

1 26. The bone-ended graft of claim 23 wherein said at least one section of material
2 contacts the ends of two or more fins and is secured into place by compression onto said
3 two or more fins.

1 27. The bone-ended graft according to claims 11 further comprising at least one
2 interference screw that is placed alongside said at least one bone-block, wherein when so
3 placed in a hole in a bone in a recipient in need of a bone-ended graft, said screw
4 compresses against an adjacent section of the hole wall, and also compresses said bone-
5 ended graft against other sections of the hole wall.

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1 28. An assemblable fixation plug for attachment with at least one length of flexible
2 material, comprising:

- 3 a. a first segment comprising at least one inner mating surface, said inner mating
4 surface of said first segment comprising at least one protrusion extending
5 therefrom; and
6 b. a second segment comprising at least one inner mating surface, said inner
7 mating surface of said second segment comprising at least one hole formed
8 thereon to receive the at least one alignment protrusion on said first segment;
9 wherein when a section of said flexible material is placed between the inner
10 mating surfaces of the first and the second segments, and the segments are joined
11 so the at least one hole receives the at least one protrusion, said section of flexible
12 material is compressed.

1 29. The assemblable fixation plug of claim 28, wherein the inner mating surfaces are
2 substantially flat.

1 30. The assemblable fixation plug of claim 28, wherein said first and second segments
2 are semi-conical shaped and comprise an exterior surface with threads defined thereon,
3 wherein when said first and second segments are brought together, said threads are
4 aligned.

1 31. The assemblable bone fixation plug of claim 28; wherein said at least one protrusion
2 comprises a pin.

1 32. The assemblable fixation plug of claim 28, wherein said inner mating surface of said
2 first segment, second segment or both comprises, teeth, ridges, grooves or another
3 irregular shape to prevent slippage of said flexible material out of said assemblable
4 fixation plug when assembled.

1 33. The assemblable fixation plug of claim 28, additionally comprising an aperture
2 formed on at least one end to receive a driving tool.

1 34. The assemblable fixation plug of claim 28, additionally comprising a depression in
2 one or both of the inner mating surfaces, and wherein said section of flexible material is
3 thickened, whereby upon tightening of the first and second segments, the thickened end is
4 restricted from sliding out of the plug.

1 35. The assemblable fixation plug of claim 28, wherein said first and second segments
2 are comprised of mineralized bone, demineralized bone or a synthetic material, or a
3 combination thereof; and said at least one length of flexible material is comprised of soft
4 tissue or of a synthetic material.

1 36. A method of preparing a soft tissue graft comprising:

- 2 a) initially preparing a section of soft tissue comprising decellularizing
- 3 said section of soft tissue;
- 4 b) layering said section of soft tissue around a mandrel to form a layered
- 5 shape of a desired thickness; and
- 6 c) treating a part of said section of soft tissue to adhere together said
- 7 layered shape of soft tissue.

1 37. The method of claim 36, additionally comprising removing said mandrel.

1 38. The method of claim 36, additionally comprising drying said section of soft tissue
2 after said decellurizing, after said treating to adhere, or after both said steps, wherein said
3 drying is by one or more of contacting said section of soft tissue in alcohol, heat drying,
4 vacuum drying, and freeze drying.

1 39. The method of claim 36, additionally comprising a virus inactivating step comprising
2 contacting said section of soft tissue with a virus inactivating agent, wherein said viral
3 inactivating agent comprises benzalkonium chloride, calcium hydroxide, sodium
4 hydroxide or hydrogen peroxide, or a combination of both.

1 40. The method of claim 36, wherein said treating to adhere is accomplished by
2 immersion of said section of soft tissue in a gelatin solution.

1 41. The method of claim 36, wherein said decellurizing is by immersion of said section
2 of soft tissue in a solution comprising, by weight, about 0.5 percent or more Tween 20
3 and about 0.5 percent or more hydrogen peroxide.

1 42. The method of claim 28, additionally comprising applying pressure to said layered
2 shape of soft tissue.

1 43. The method of claim 36 wherein said soft tissue is comprised of dermis, fascia,
2 pericardium, woven soft tissue, urinary bladder matrix, peritoneum, or SIS.

1 44. A soft tissue graft produced by the method of claim 36.

1 45. A method of preparing a soft tissue graft comprising:
2 a) obtaining a decellularized, virally inactivated section of soft tissue; and
3 b) subjecting all or a portion of said soft tissue to a cross-linking treatment.

1 46. The method of claim 45, wherein said cross-linking treatment comprises contact with
2 glutaraldehyde, formaldehyde or other mono- and dialdehydes; glycerol polyglycidyl
3 ethers, polyethylene glycol diglycidyl ethers or other polyepoxy and diepoxy glycidyl
4 ethers; titanium dioxide, chromium dioxide, aluminum dioxide, zirconium salt, or other
5 organic tannins and other phenolic oxides derived from plants; chemicals for
6 esterification or carboxyl groups followed by reaction with hydrazide to form activated
7 acyl azide functionalities in the collagen; dicyclohexyl carbodiimide or its derivatives;
8 heterobifunctional crosslinking agents; hexamethylene diisocyanate; or sugars.

1 47. The method of claim 46, wherein said cross-linking treatment comprises contact with
2 transglutiminase or other enzymatic cross-linking agents.

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- 1 48. A method of preparing a soft tissue graft comprising:
2 a) decellularizing a section of soft tissue comprising a first end and a
3 second end;
4 b) layering said section of soft tissue around a mandrel to form a layered
5 shape of a desired thickness; and
6 c) contacting said first end, second end or both of said layered shape of
7 soft tissue in a hardening treatment.
- 1 49. The method of claim 48, wherein said hardening treatment comprises partial or
2 complete calcification.
- 1 50. The method of claim 49, wherein said calcification comprises contacting a section of
2 said soft tissue with a calcium solution, and thereafter contacting said section with a
3 phosphate solution.
- 1 51. The method of claim 50, wherein said calcium solution is saturated calcium
2 hydroxide, and said phosphate solution is phosphate buffer adjusted to approximately pH
3 7.0.
- 1 52. The method of claim 48, wherein said section of soft tissue is comprised of dermis,
2 fascia, pericardium, woven soft tissue, urinary bladder matrix, peritoneum, or SIS.
- 1 53. A soft tissue graft produced by the method of claim 48.
- 1 54. A method of preparing a dermis derived graft comprising:
2 a) obtaining a section of dermis tissue comprising a first end and a second end;
3 and
4 b) attaching a bone block to either said first end or said second end or both.

1 55. The method of claim 54, wherein said attaching is by chemical annealing, chemical
2 adhesive, suturing, pinning to, or wrapping and tying the processed dermis around said
3 bone block.

1 56. A dermis derived graft produced by the method of claim 54.

1 57. A method of conducting orthopedic surgery on an animal comprising:
2 obtaining a dermis derived bone-ended graft, said graft comprising processed
3 dermis comprising a first end and a second end, and at least one bone block
4 affixable to said first end, to said second end, or to both said ends, and
5 attaching said at least one bone block to a desired position in an animal in need
6 thereof with a fixation screw.

1 58. The method of claim 57, wherein said at least one bone block is pre-shaped into a
2 dowel, and wherein said bone block has a groove suitable for accommodating the fixation
3 screw, and wherein the fixation screw passes through said groove.

1 59. The method of claim 58, wherein said bone block of said first end and second end are
2 different in size.

1 60. The method of claim 57, wherein said attaching of the at least one bone block is to at
2 least one bone of the animal.

1 61. The method of claim 60, wherein the at least one bone of the animal are selected
2 from the group of bones consisting of patella, femur and tibia.

1 62. A method of conducting orthopedic surgery on an animal comprising:
2 obtaining a bone-ended graft, said graft comprising a length of soft tissue
3 having two ends and one or more bone blocks attached to said bone-ended
4 graft,
5 wherein at least one of said one or more bone blocks is pre-shaped into a dowel.

1 63. The method of claim 62, wherein said orthopedic surgery is a repair or replacement
2 of an Anterior Cruciate Ligament or Posterior Cruciate Ligament

1 64. A dermis derived bone-ended graft useful in orthopedic surgery comprising at least
2 one bone block and an elongated section of processed dermis attached to said at least one
3 bone block.

1 65. The graft of claim 64, wherein at least one of the at least one bone block is
2 comprised of cortical, cancellous, cortico-cancellous, or demineralized bone, obtained
3 from human or xenograft sources, optionally in combination with a synthetic material.

1 66. The graft of claim 65, wherein at least one of the at least one bone block is
2 comprised of at least two segments.

1 67. The graft of claim 66, wherein said at least two segments are in the shape of disks.

1 68. A soft tissue implant for spanning two or more vertebrae, or for spanning a bone
2 fracture site, comprising:
3 a. a middle section capable of flexion;
4 b. a contiguous top section having at least one aperture for an attaching
5 means; and
6 c. a contiguous bottom section having at least one aperture for an attaching
7 means;
8 wherein in spanning two or more vertebrae, or in spanning a bone fracture
9 site, said soft tissue implant is attached to sites on said vertebrae or bone by
10 attaching means, and said processed dermis implant covers at least a front, a
11 back, or a side of at least one intervertebral disc junction or bone fracture site.

1 69. The soft tissue implant of claim 68 comprised of dermis, fascia, pericardium, woven
2 soft tissue, urinary bladder matrix, peritoneum, or SIS.

74. The implant of claim 73, wherein said implant is fabricated from a material selected from the group consisting of segmentally demineralized bone, fascia, pericardium, ligament, tendon, muscle; dura; xenograft demineralized bone; xenograft segmentally demineralized bone; or any combination of these implant materials, and optionally in combination with biocompatible synthetic materials